



K062231

ATTACHMENT 6

**510(k) SUMMARY**

**AUG 31 2006**

**MINRAD INC.'s MR Fiber Optic Intubating Laryngoscope Handle,  
Standard**

**1. Submitter's Information**

**MINRAD INC.  
847 Main Street, Buffalo NY 14203**

**Phone: 716-855-1068  
Facsimile: 716-855-1078**

**Contact Person: John McNeirney, VP and CTO**

**Date Prepared: 31 July 2006**

**2. Name of Device**

**MR Fiber Optic Intubating Laryngoscope Handle, Standard**

**3. Common or Usual Name**

**Laryngoscope, Rigid**

**4. Classification Name**

**Laryngoscope, Rigid (21 CFR 868.5540, Product Code CCW)**

**5. Predicate Devices**

**MINRAD INC. MR Fiber Optic Laryngoscope Handle (K970619)  
Laryngoscope, Welch Allyn  
Laryngoscope, Sun Med**

**6. Intended Use**

**The MR Fiber Optic Intubating Laryngoscope Handle, Standard ("MINRAD INC. MR Fiber Optic Intubating Laryngoscope Handle, Standard") is used to facilitate and aid in tracheal intubation in a Magnetic Resonance Imaging (MRI) or an interventional Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.**



## 7. Technological Characteristics and Substantial Equivalence

The technological characteristics of all of the Laryngoscopes are similar to the **MINRAD INC. MR Fiber Optic Intubating Laryngoscope Handle, Standard**.

The **MR Fiber Optic Intubating Laryngoscope Handle, Standard** is substantially equivalent to the other currently marketed **Laryngoscope Handles**, which are referenced above. The **MR Fiber Optic Intubating Laryngoscope Handle, Standard** and its predicate devices are all **Laryngoscopes**. Thus, the **MR Fiber Optic Intubating Laryngoscope Handle, Standard** raises no new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 31 2006

Mr. John McNeirney  
Senior Vice President and Chief Technical Officer  
Minrad, Incorporated  
847 Main Street  
Buffalo, New York 14203

Re: K062231

Trade/Device Name: Minrad Inc. MR Fiber Optic Intubating Laryngoscope  
Handle, Standard

Regulation Number: 21 CFR 868.5540

Regulation Name: Rigid Laryngoscope

Regulatory Class: I

Product Code: CCW

Dated: August 1, 2006

Received: August 3, 2006

Dear Mr. McNeirney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

ATTACHMENT 7

**Indications for Use**

510(k) Number (if known):

Device Name: **MINRAD INC. MR Fiber Optic Intubating Laryngoscope Handle, Standard**

Indications for Use:

The MR MR Fiber Optic Intubating Laryngoscope Handle, Standard ("MINRAD INC. MR Fiber Optic Intubating Laryngoscope Handle, Standard") is used, together with a Laryngoscope blade, to facilitate and aid in tracheal intubation in a Magnetic Resonance Imaging (MRI) or an interventional Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Dr. C. L. Smith  
Division Sign-Off  
Division of Anesthesiology, General Hospital,  
Division Control, Dental Devices

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